IN THE

# Supreme Court of the United States

**October Term, 1979**

**No. 79-136**

LUTRELLE F. PARKER, ACTING COMMISSIONER OF PATENTS AND TRADEMARKS,
*Petitioner*

v.

MALCOLM E. BERGY, *ET AL.*,

LUTRELLE F. PARKER, ACTING COMMISSIONER OF PATENTS AND TRADEMARKS,
*Petitioner*

v.

ANANDA M. CHAKRABARTY

## BRIEF ON BEHALF OF THE PEOPLES BUSINESS COMMISSION, AMICUS CURIAE

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## BRIEF ON BEHALF OF THE PEOPLES BUSINESS COMMISSION, AMICUS CURIAE

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### I. INTEREST OF THE AMICUS CURIAE AND INTRODUCTION

The Peoples Business Commission (PBC) is a non-profit educational foundation incorporated in the District of Columbia. PBC develops a wide range of educational materials designed to raise public awareness of emerging economic and technological trends within the United States and the impact these trends will have on the lives of the citizens of this country.

PBC has emerged as one of the nation's leading critics of the various biological technologies known as "genetic engineering." It is the belief of PBC that the social application of genetic engineering is rapidly proceeding without due consideration or public understanding of the wide range of ecological, evolutionary, ethical, philosophical, political and economic questions inherent in any application of bio- and genetic manipulation.

Ted Howard and Jeremy Rifkin, co-directors of PBC, are co-authors of "Who Should Play God?," the largest selling book on genetic engineering. American high school and college professors are using this book as a standard text on the ethical and social implications of genetic manipulation. "Who Should Play God?" has been translated into six foreign languages, including Japanese, French and Spanish. Howard and Rifkin's articles on various aspects of genetic engineering have appeared in *The Los Angeles Times, Newsday, The Progressive, The St. Louis Post Dispatch,* and scores of other publications. Because of their familiarity with the social implications of genetic engineering, PBC staff members have been called upon to testify before Congressional Committees, the National Academy of Sciences, the Department of H.E.W. Ethics Advisory Board, and the Eastern Virginia State Health Agency.

The interest of the amicus herein is PBC's belief that the present cases are of critical importance to the potential development and direction of the burgeoning genetic engingeering industry. Most financial and scientific observers concur that during the coming two decades, genetic engineering technologies will have a profit potential and social impact akin to the development of transistors and computers during the past twenty years. PBC contends that a ruling in favor of life form patents in *Bergy* and/or



*Chakrabarty* would serve as a precedent in a host of related areas of genetic manipulation, most particularly in the field of recombinant DNA, or "gene splicing." Such a ruling would significantly contribute to the profit potential of the genetic industry, thus generating a greater momentum in research and development of genetic engineering technologies. This, in turn, will lead to the rapid proliferation of genetic techniques in the areas of energy, agriculture, medicine, industrial processes and many other aspects of the nation's economic life.

It is PBC's contention that such a proliferation of genetically-based technologies is not in the public interest for a host of reasons. PBC believes that the ecological, evolutionary, ethical, philosophical, political and economic questions that surround the patenting of living organisms have been given insufficient consideration by the Congress, the country as a whole and the lower court in issuing its ruling in favor of such patents.

All parties have consented to the filing of this *amicus* by letter, the originals of which are being filed concurrently with the clerk.

## II. THE ISSUES PRESENTED

The issues addressed by this amicus are:

Whether genetically engineered forms of life are a "manufacture" or "composition of matter" intended by Congress to be subject to patentability within 35 U.S.C. 101.

Whether it is in the "public interest" and serves the "useful Arts" to patent living organisms.

## III. STATEMENT OF FACTS

On March 29, 1979, the Court of Customs and Patent Appeals ruled that General Electric and Upjohn be granted the nation's first patent for genetically engineered forms of life. The General Electric life form, a *Pseudomonas* bacterium developed by Dr. Ananda M. Chakrabarty, contains a new combination of plasmids not previously found in nature. This microorganism produces enzymes which break down a number of the hydrocarbon components of petroleum. The Upjohn microorganism, *Streptomyces vellosus,* was isolated by Dr. Malcolm E. Bergy et al., and is used in a process to produce by fermentation the antibiotic lincomycin.

The two life form patents were granted under the provision of Section 101 of Volume 35 of the U.S. Code which reads: "Whoever invents or discovers any new and useful process, machine, manufacture or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor. . ." In ruling in favor of the patent applications of the two companies, the majority held that there was no justification for excluding an "invention" merely "because it is 'alive'." The lower court further argued that "from the standpoint of construing the patent statutes, we do not see. . . *any sound reason* for making the distinction . . . here between the living and the dead."

The Patent and Trademark Office had refused to grant GE and Upjohn patents on living organisms because of its belief that Congress never intended that forms of life be patentable under 35 U.S.C. 101. The PTO argued that because "the number of living things is vast," the awarding of life form patents "opens an enormous range of subject matter to patentability" including "living organisms — life itself."



The Solicitor General of the United States petitioned this Court for a writ of certiorari. On 29 October of 1979, the Court granted the Solicitor's petition for writ of certiorari in *Parker* v. *Bergy et al.*

## IV. SUMMARY OF ARGUMENT

The Solicitor General of the United States contends that the Congress of the United States never intended that living organisms, whether modified through genetic engineering or not, be patentable under 35 U.S.C. 101. We support the Solicitor on this point, and will not further argue it herein.

The arguments developed in this brief are three-fold:

1. That the single area in which Congress has specifically authorized the patenting of living organisms through legislation — the Plant Patent Act of 1930 and the Plant Variety Protection Act of 1970 — provides ample evidence that the patenting of any form of life (plant or otherwise) necessarily leads to certain genetic and social impacts that are not in the best interests of society or succeeding generations.

2. That the technology of genetic engineering, taken as a whole, is not in the public interest, and should not be unduly encouraged by giving unwarranted economic incentive to corporations in the field of genetic research and development through the vehicle of awarding potentially lucrative patents on living organisms.

3. That if patents are granted on microorganisms there is no scientific or legally viable definition of "life" that will preclude extending patents to higher forms of life, and that, indeed, the various technologies of genetic engineering have already created a climate in which patents on

higher organisms can consistently be claimed once the precedent has been set with microorganisms.

## V. ARGUMENT

### 1. THE RELATIVELY RECENT HISTORY OF GRANTING PLANT PATENTS ILLUSTRATES THE DELETERIOUS GENETIC AND SOCIAL EFFECTS OF PATENTING LIVING ORGANISMS.

Until the March 29, 1979 Court of Customs and Patent Appeals decision awarding patents on genetically engineered microorganisms to General Electric and Upjohn, the only living organisms considered patentable under Congressional legislation were certain types of plants and seeds. The history of our national plant patenting policy serves as a backdrop to the issue now before this Court, and should be given serious consideration before any decision regarding the patenting of other living organisms is reached.

In an attempt to encourage plant breeding and the development of new types of crops with desirable characteristics, Congress passed the Plant Patent Act of 1930. This Act provides for the patenting of certain types of *asexually* reproduced plants. Four decades later, Congress extended this legislation with the Plant Variety Protection Act of 1970, which provides for, among other things, certificates akin to patents for certain kinds of *sexually* produced plants.

These acts were passed on the assumption that patents would provide the economic incentive that would lead to the production of numerous man-made plant varieties that would be of social benefit. In fact, just the opposite has taken place. According to a publication of the National Sharecroppers Fund, the genetic and social consequences



of global plant patent laws pose "a serious threat to world food supplies and to the future of agriculture."[1]

The deleterious effects of the various plant patent laws have been three-fold:

First, the availability of plant patents has led to the systematic, and irreversible, elimination of many varieties of useful plants and crops simply because they were products of nature and thus could not be patented. Because of this basic economic fact of life, seed and grain companies encourage the world's farmers to buy their "superior" products rather than using naturally existing native strains. Convinced of the 'superior' qualities of newly bred and designed varieties of crop plants, farmers cease to grow their traditional crops. Writes Cary Fowler of the Frank Porter Graham Demonstration Farm and Training Center of Wadesboro, North Carolina, "leftover seeds of the traditional variety may be used as food for the family or their animals. In a moment's time, thousands of years of crop development and seed selection become meaningless and another variety becomes extinct."[2] *Thus, as a direct result of plant patent legislation, thousands of useful varieties of plants have been eliminated from the planetary gene pool.*

Second, and as a corollary to the first effect, as patentable plants have been widely propagated, and nonpatentable varieties have been eliminated, genetic diversity is lost, and monoculturing becomes the rule. Again, Fowler: "Modern agriculture needs predictability; therefore, plant breeders strive for uniformity. Plants are bred and inbred to develop the desired characteristics. The result has been

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[1] Cary Fowler, *The Graham Center Seed Directory*, Rural Advancement Fund of the National Sharecroppers Fund, (Wadesboro, North Carolina: 1979).

[2] *Id.*

the creation of new varieties that are extremely genetically limited. . . Where thousands of varieties of wheat once grew, only a few can now be seen. When these traditional plant varieties are lost, their genetic material is lost forever. Herein lies the danger. Each variety of wheat, for example, is genetically unique. It contains genetic 'material' not found in other varieties. If, because of genetic limitations which result from inbreeding, new varieties are no longer resistant to certain insects or diseases (conceivably even insects or diseases never before known to attack wheat), then real catastrophe could strike."[3]

In fact, due to the elimination of genetic diversity stemming from the patentability of certain types of plants, disaster has already struck many farmers. The monocultured sugarcane industry has nearly been wiped out twice, and the banana industry has similarly been threatened due to lack of genetic diversity. In 1970, a corn blight struck the U.S. crop. Nearly 15 percent of the nation's crop was destroyed; in some southern states the losses topped 50 percent. According to the National Academy of Sciences: "The key lesson of 1970 [the year of the corn blight] is that genetic uniformity is the basis of vulnerability to epidemics. [Today] . . . most crops are impressively uniform genetically and impressively vulnerable."[4] According to a National Academy of Sciences study, just one type of sweet potato produces 69 percent of our domestic crop; two varieties of dry beans yield 60 percent of our crop; three types of millet, 100 percent; 6 types of corn, 71 percent.[5] *Again, the internal logic*

[3] *Id.*

[4] Committee on Genetic Vulnerability of Major Crops, *Genetic Vulnerability of Major Crops,* National Academy of Sciences, 1972.

[5] Committee on Germplasm Resources, *Conservation of Germplasm Resources,* National Academy of Sciences, 1978.



*of plant patenting has led directly to the loss of genetic diversity and the reliance of societies upon dangerously inbred and frail monocrops.*

The third effect of the Plant Patent Act is not genetic, but rather social. In a report recently published by the London-based International Coalition for Development Action, "Seeds of the Earth," author P.R. Mooney outlines how plant patent legislation has made plant breeding such a lucrative endeavour that ownership of the world's basic plant food supply is increasingly being concentrated within a small number of large multinational corporations. Seventy-nine percent of the U.S. patents issued on beans have gone to just four companies, and nearly fifty once-independent seed companies have recently been acquired by corporations such as ITT, Upjohn, Purex, and so on. According to the ICDA report, these large companies build up private gene banks to which access is limited to the companies' plant breeders. Once again, thanks to the patent laws, the bulk of the world's food supply is now owned and developed by a handful of corporations which alone, without any public input, determine which strains are used and how. ICDA claims: "in some crops a single enterprise dominates the total world germplasm holdings." United Brands, for instance, privately possesses two-thirds of the world's banana germplasm in storage.[6]

This three-fold trend – the loss of genetic diversity, monoculturing of disease and pest susceptible crops, and the private manipulation of food resources that properly belong to the entire family of man – continues unabated. In Europe, an alarming escalation of this momentum is taking place. Because living organisms such as plants

[6] P.R. Mooney, "Seeds of the Earth," International Coalition for Development Action, (London: 1979).

change genetically in subtle ways in response to their environment, companies have been confronted with the difficulty of enforcing their patents on "products" which differ from year to year. In an attempt to reduce these problems, legislation approved by Common Market member countries will, by 1981, make thousands of plant varieties now commonly grown in Europe *illegal*. These varieties can no longer be grown commercially; their seeds can not be sold; backyard gardeners can be fined for growing the banned vegetables. According to Dr. Erna Bennett of the Food and Agricultural Organization of the United Nations, up to three-quarters of all vegetable varieties now grown in Europe will go extinct as a result of this legislation. "Genetic wipe-out," she says, "might well be tomorrow's greatest single problem. . . "[7]

Because of these alarming developments, the International Coalition for Development Action recommends that patent laws in all countries relating to plants should be uniformly repealed, and plants should be recognized as "resources of common heritage to all peoples."[8]

The history of the results of the several plant patent acts clearly shows that far from leading to a multiplicity of social benefits, the patenting of plants has in fact cruelly robbed succeeding generations of their own right to a diversified, healthy and vital gene pool. We have, in effect, made an irreversible choice for all those humans yet to be born.

Because plants are the only living organisms now patentable, the above mentioned consequences of plant patent-

[7]Cary Fowler, "From Patented Seeds, Big Business Grows," *ruralamerica*, September 1979.

[8]Mooney. See also: "To Promote the Progress of . . . Useful Arts," *Report of the President's Commission on the Patent System* (1966) at 13, 14; *Gottschalk* v. *Benson*, 409 US 63 at 72, 73.



ing must be seriously considered as a possible pattern that may be repeated should other forms of life be deemed patentable by this Court. The lessons so harshly learned from plant patenting are particularly applicable in the following areas of genetic engineering:

* The novel microorganisms that will be created through various genetic engineering techniques may well be, in many cases, "superbugs," that is, they will be bred or engineered in such a way that they may become the dominant form of life within their niche in the ecosystem. The General Electric *Pseudomonas*, for instance, is acknowledged to contain properties resulting from the combination of a number of other bacterium. Once these microorganisms are unleashed into the ecosystem, on purpose or by accident, they may out compete other forms of life because of their unique properties. This could seriously damage the vitality of the gene pool.

* The monoculturing of certain types of high-yield, but disease and pest susceptible plants, will be repeated by the genetic engineering industry through the monoculturing of "superior" microorganisms. Geneticists are currently predicting, for instance, that within the near-term future, various chemicals, hormones and drugs will be solely produced in the laboratory by genetically engineered microorganisms because such techniques are "cost-effective." Thus, within the foreseeable future, the world will be dependent upon a very limited number of biological entities to produce vital medicine and chemical necessities. The monoculturing of microorganisms may well prove as deficient as that already acknowledged in food crops.

* If patents are extended to genetically modified higher organisms (such as domestic livestock) – and we will argue later in this brief that the awarding of

microorganism patents sets a dangerous precedent for this occurrence – there can be little doubt that the full history of the patenting of plants will be repeated. One can anticipate that a small number of cattle genotypes will be widely reproduced because of their "superior" characteristics; other, less useful, cattle will become extinct; the diversity of the animal gene pool will be as narrowly defined as that now existant among corn, wheat and so on. Dr. Clement Markert of Yale, for instance, is working on methods for the asexual production (cloning) of domestic livestock such as cattle and sheep. In *Fortune* magazine Dr. Markert was quoted as saying: "I could wipe out all of Yale's deficits with the valuable bulls raised from the embryos I could produce in one weekend."[9] That may well be the case, but the fact remains that any such attempt will seriously and irrevocably disrupt the gene pool.

* Finally, the history of domestic plant patenting is particularly relevant to *Bergy* because many of the very same companies that have gained control of the world's food germplasm are also those now engaged in microorganism genetic engineering. Upjohn, currently seeking the Bergy patent, is the owner of two major seed companies and their plant patents. As a result Upjohn and three other companies hold 79% of all bean patents, Upjohn and five other companies hold two-thirds of all patents issued for lettuce, and Upjohn shares with only one other company 43% of all the patents issued for peas. Other companies in similar positions include Pfizer, Ciba-Geigy and Monsanto.[10] There is no reason to believe that these companies will develop the genetic engineering life form industry any

[9]Gene Bylinksy, "The Cloning Era is Almost Here,"*Fortune*, June 19, 1978.

[10]Cary Fowler, Testimony on behalf of The National Sharecroppers Fund, before the House Agriculture Subcommittee, July 19, 1979.



differently than they have already done in the area of patentable plants.

It is an accepted fact that a patent cannot be given for laws of nature, phenomena of nature, scientific principles or mathematical equations. Quoting from Rosenberg, "The reason is founded upon the proposition that in granting patent right, the public must not be deprived of any rights that it theretofore freely enjoyed."[11] The history of the consequences of plant patent legislation indicates that because plants have been subject to patentability, the public has already lost a right which it once freely enjoyed – the right to a diversified gene pool composed of thousands of varieties of naturally occuring life forms. This basic right of our generation and most especially succeeding generations should not be even more greatly infringed upon by the awarding of patents on genetically engineered living organisms.[12]

## 2. THE TECHNOLOGY OF GENETIC ENGINEERING, TAKEN AS A WHOLE, IS NOT IN THE PUBLIC INTEREST.

The majority opinion in *Bergy*, October 6, 1977, held: "We think that it is in the public interest to include microorganisms within the terms "manufacture" and 'composition of matter' in 101."[13] Below, in an amicus brief supporting *Chakrabarty*, the American Patent Law

[11]P. Rosenberg, *Patent Law Fundamentals*, (1975).

[12]All forms of life are the embodiment or epitomy of the laws of nature which this Court has repeatedly held are not patentable subject matter under 35 U.S.C. 101 and its predecessors, absent express Congressional authorization. See, e.g., *Parker* v. *Flook*, 437 U.S. 584, and cases cited therein.

[13]563 F.2d 1031. As reported in Solicitor General's Petition for Writ of Cert. to Supreme Court, pp. 120a, 121a.

Association claims, "there can be no doubt that molecular biology and genetic engineering techniques constitute a 'useful art' in today's world."[14] Other interested parties in these cases have made similar claims.

The question of whether the public will be well-served by the patenting of living organisms and the technology of genetic engineering should most properly be left to the public-at-large and its elected representatives. However, since the claims that genetic engineering is "in the public interest" and a "useful art" have been made by those who seek life form patents, and since these claims seem to be an implicit part of the debate over the granting of such patents, PBC cannot allow such assumptions to go unchallenged.

*PBC contends that the granting of patents on living organisms and the flurry of research and development such patents will generate within the budding industry of genetic engineering are not in the public interest.*

Few Americans are aware of the potential impact that the patenting of microorganisms, in particular, and the genetic engineering industry, in general, will have on their lives and their society. The term "Biological Revolution" has rightly been used to characterize the astounding and awesome strides being made in the fields of biology and genetics. Because of this Biological Revolution, highly technological societies such as ours are on the threshold of controlling the biological and genetic quality of all living material, from the humblest microorganism to the most proud human. As Dr. George Wald, the Harvard Nobel-laureate has said, "we are moving from the organic design of life to technological specification of living material."[15]

[14]At page 4.

[15]Cited in Ted Howard and Jeremy Rifkin, *Who Should Play God?*, (New York: Dell, 1977).



Just as we have manufactured metals and plastics, now there are those who contemplate manufacturing life itself.

This potential, to turn living material into yet another factor of economic production, has led many scientists and corporate officials to forecast a multi-billion dollar genetics industry hovering just over the horizon. Already, dozens of the nation's Fortune 500 firms – Standard Oil, General Electric, Upjohn, among them – along with a growing number of smaller, recently founded genetic companies – Cetus, Genentech, Genex, Biogen – are engaging in research which is expected to be of tremendous profit-making potential.[16] A few quotes from company officials serve to illustrate the enthusiasm surrounding genetic engineering:

> Gordon C. McKeague, corporate development manager for Standard Oil of Indiana: [Genetic technologies represent] "the growth business of the future."[17]
>
> Nelson Schneider, investment analyst for E.F. Hutton: "The potential applications of this technology are revolutionary and incredibly broad. . ." Speaking of various types of genetic

[16]For basic information on the growth of the genetic engineering industry, see: Ted Howard, "Patenting Life," *The Progressive*, September, 1979; Jeremy Rifkin, Larry Gordon and Dan Smith, "DNA," *Mother Jones*, February-March, 1977; "Where genetic engineering will change industry," *Business Week*, October 22, 1979; "DNA is on the way to chemicals," *Chemical Week*, September 26, 1979; Sharon Begley, "The DNA Industry," *Newsweek*, August 20, 1979; Nelson M. Schneider, "DNA – The Genetic Revolution," E.F. Hutton Review, August 1, 1979; Nelson M. Schneider, "Biotechnology," E.F. Hutton, November, 1979; David Dickson, "Recombinant DNA research: private actions raise public eyebrows," *Nature*, vol. 278, 5 April 1979.

[17]Quoted in "Where genetic engineering will change industry," *Business Week*, October 22, 1979.

technologies, Schneider uses rhetoric including: "a major new profit opportunity. . . the most exciting investment potential . . . substantial growth possibilities. . ."[18]

Irving Johnson, vice president of research at Eli Lilly: "Potential applications of (genetic) techniques are limited only by the imagination of the people using them."[19]

A great deal of this profit making potential is based upon the controversial technique of recombinant DNA or "gene splicing." While neither the GE nor the Upjohn organism under consideration in this case are products of "gene splicing," the considered opinion of the great majority of scientists engaged in genetic engineering is that the granting of patents to GE and Upjohn here will be perceived by the industry as a signal that organisms generated through recombinant DNA will be patentable as well, since these microorganisms will be as much a "manufacture" or "composition of matter" as are the Bergy and Chakrabarty "inventions."

A reading of genetic industry literature, and personal interviews with many of the principals in the field of genetic engineering, leads PBC to conclude that during the coming decade, Americans will come in contact with genetic manipulation every time they drive their car, sit down to dinner, reach into the medicine cabinet, enter the hospital, or visit the neighborhood shopping mall. An E.F. Hutton investment publication, "Biotechnology," outlines genetic engineering research that is moving toward commercial

[18]Nelson M. Schneider, "Biotechnology," E.F. Hutton, November, 1979.

[19]Quoted in Nicholas Wade, "Recombinant DNA: Warming Up for Big Payoff," *Science*, Vol. 206, 9 November, 1979.



application including: the GE and Upjohn microorganism "products"; the potential for producing alcohol, ethylene glycol, plastic precursors and billions of dollars worth of chemicals, hormones, enzymes and drugs; and nitrogen fixation of plant crops.[20]

It is arguable that such commercial applications of genetic engineering are in the public interest. Every "problem" deemed solvable through genetic engineering can, in fact, be tackled in numerous other ways. Oil spills can be consumed by GE's microorganism, for example, or Congress can legislate standards for oil tankers restricting their length and carrying capacity to a more manageable and navigable size. More important, alternatives to technologies based upon microorganisms are inherently safer ecologically, do not risk contamination of the gene pool, and do not carry with them the ethical implications of patenting life.

In short, in solving some social problems, genetic engineering will create others of a greater dimensional magnitude not yet understood by the general public. While it is true that every technology has adverse "side effects," the dangers posed by genetic engineering are of an ireversible nature. These dangers should therefore be recognized by the Court as important factors in any consideration of granting life form patents which will encourage industry to more rapidly develop genetic technologies.

Genetic engineering will, within the lifetime of many of us, give some individuals or institutions the final and awesome power to irreversibly violate three billion years of evolutionary wisdom through the creation of novel life forms, or the genetic alteration of living entities now existant. Humanity is about to become an active participant in

[20]Schneider, "Biotechnology."

evolution through the use of this powerful technology, a process which will pre-determine for all succeeding generations the quality of the gene pool they inherit.

The most immediate danger to the public interest is that the proliferation of genetic engineering techniques and novel forms of life will irreversibly pollute the planetary gene pool in radically new ways. Dr. Jonathan King, a biologist at MIT, is one of a number of scientists who foresees tremendous "biohazard" problems emanating from the genetic industry. King points out that by developing novel forms of life through recombinant DNA, entities which do not now exist in the ecosystem, we run the risk of creating the ultimate in "pollution and disease disasters." According to King, as scientists and corporations join together to profit from the new life forms, they are completely discounting the fact that "there are no non-polluting technologies. With recombinant DNA, there will be a pollution of a new kind, biological pollution, pollution that grows as the organism reproduces itself. Yes, you could say that it's a renewable resource, but the pollution from it is renewable, too."[21]

The General Electric Company *Pseudomonas* may well be a case in point. GE hopes to one day unleash its microorganism on an oil slick, thus preventing a tanker spill from polluting the shoreline. Environmentalists, however, are voicing concern about where the "oil eater" will go once the petroleum is consumed. GE's test results indicate that in laboratory conditions the "bug" will die once its food supply is eaten. But what if natural conditions turn out to be more complicated than the laboratory

[21]Telephone interview with King. See also: Jonathan King, Ethan Signer, Stuart Newman, and David Ozonoff to Dr. John Nutter, NIH, May 15, 1979 (documents 685 and 686, Office of Recombinant DNA Activities, NIH).



controlled environment? Or what if the genetic industry follows the standard operating procedure of petrochemical firms which are known to churn out tens of thousands of synthetic organic chemical compounds annually, but only test a handful to determine if they are carcinogenic or mutagenic? We are just now witnessing the horrific effects of PCBs, dioxin, and other compounds that went untested in the rush to the market. In a genetic accident, the price will be much higher. Once out of the laboratory, there is no recalling a life form.

Disease and pollution scenarios are no mere conjecture. Recently conducted experiments concerning the safety of recombinant DNA have proven the biohazard potential of such a technique. According to Francine Simring of the Coalition for Responsible Genetic Research, NIH-sponsored research has demonstrated that: (1) gene-splice products cause tumors in experimental mice; (2) naked polyoma (multiple tumor) DNA causes infection; (3) novel microorganisms that escape the laboratory can survive for some four days in the human gut and in sewage.[22] Dr. Stuart Newman of New York Medical College points to experiments that indicate that "quantitatively new routes of dissemination" of cancer-causing agents can result from certain types of recombinant DNA research.[23]

[22]Francine Simring, "Guidelines out the Window?" *Not Man Apart*, October 1979.

[23]Stuart Newman, *Federal Register*, vol. 44, No. 213 (November 1, 1979): 63075, 63076. For further material on biohazard possibilities, see: Stuart Newman, letter to *Nature* 281 (20 September 1979): Nicholas Wade, "Recombinant DNA: A Critic Questions the Right to Free Inquiry," *Science* Vol. 194 (15 October 1976); *CRGR Newsletter*, Coalition for Responsible Genetic Research, New York, September 1979; Judith Randal, "All the Way with DNA?" *Medical Dimensions*, April, 1978; George Wald, "The Case Against Genetic Engineering," *The Sciences*, September-October, 1976; Liebe Cavalieri, "New Strains of Life – or Death?" *New York Times Magazine*, August 22,

What makes these issues of potential biohazard and gene pool disruption so critical at this time is the fact that there is absolutely no governmental regulation of industrial genetic engineering research and development. The quest for life form patent rights has had inhibiting effects on the development of Federal safety standards to regulate genetic engineering experimentation (specifically, recombinant DNA). The assertion by numerous companies that safety guidelines can not be monitored or enforced by the government without compromising corporate proprietary information has led the National Institutes of Health to conclude that privately funded genetic research need be subject to only voluntary compliance with already existing Federal safety standards. It is a known fact that companies are not now complying voluntarily with these standards. One genetic engineering firm has gone so far as to publicly flaunt its violation of NIH guidelines.[24]

At this stage of development, and by all indications the situation is not likely to change, the public-at-large has absolutely no control over which genetic technologies are developed, how they are developed, or how they will be

1976; Robert Sinsheimer, "An Evolutionary Perspective for Genetic Engineering," *New Scientist,* January 20, 1977; Frances R. Warshaw, *Gene Implantation: Proceed with Caution,* Science for the People, Boston, November, 1976.

[24]For an overview of Federal attempts to regulate genetic engineering research, see: Susan Wright, "Recombinant DNA Policy: From Prevention to Crisis Intervention," *Environment* vol. 21, No. 9 (November 1979); Katherine Ellison, "Firm Pushes Ahead in Genetics," *The Washington Post,* July 5, 1979; Nicholas Wade, "Major Relaxations in DNA Rules," *Science* Vol. 205, 21 September, 1979; David Dickson, "US expected to exempt most recombinant DNA experiments from federal regulation, *Nature,* vol. 281, (13 September 1979); "NIH Proposes new DNA rules for Industry," *Chemical Week,* August 9, 1978. For a history of NIH policy-making on recombinant DNA, see *Environment* (May 1978), pp. 6-15 and 39-41; and *Environment* (April 1979), pp. 2-5.



applied. Indeed, at this point, while science now knows enough to create new forms of life and disrupt the evolutionary process, no one can really foresee the impact these technologies will have on the ecosystem, the biosphere and the quality of the gene pool. There are many questions that simply cannot be asked because there has been insufficient time to consider all of the possibilities. The 'technological fix' has become the rule in this field: "if it can be done, then it should be done."

If the lower court ruling is upheld, and patents on living organisms are awarded to General Electric and Upjohn, all chance of meaningful public education and participation in the policy decisions surrounding genetic engineering will be lost, for the granting of patents is sure to escalate the drive toward commercial application. The genie will be out of the bottle before most Americans have even realized that the bottle was uncorked.

It is true that all technologies have their unanticipated costs. Society recognizes these costs as part and parcel of the price of technological innovation, and generally applies cost/benefit analysis to new techniques. However, cost/benefit analysis cannot be used in judging genetic engineering, because the cost is of an ultimate nature – the pollution of the planetary gene pool – and will have to be borne by every human yet to come.

### THE PATENTING OF LOWER ORGANISMS WILL INVARIABLY LEAD TO THE PATENTING OF HIGHER FORMS OF LIFE.

Beyond the biohazard and gene pool disruption potential of genetic engineering, lies a complicated web of intersecting moral, ethical and philosophical issues concerning the patenting of living organisms. PBC contends that there is no scientifically or legally viable definition of "life" that can preclude the patenting of higher forms of

life should the Court set a precedent by granting patent rights to microorganisms.

There is little doubt that if the science of genetic engineering had progressed sufficiently to the point where higher forms of life could be significantly modified, the entire issue of patenting living organisms would be viewed quite differently in this case. However, simply because the "state of the art" has not yet progressed to this point does not mean that this point won't be reached, and reached far sooner than most people expect. Scenarios which once appeared far-fetched – the manufacturing of mammals, including human beings, to specification; the creation of super-intelligent beings; the asexual reproduction of organisms through cloning; the advent of genetic surgery designed to alter the heredity of complex organisms – will become science fact, if not tomorrow, then certainly within the lifetimes of the majority of Americans.[25]

[25]For information on possible human applications of genetic engineering, see: Howard and Rifkin, *Who Should Play God?*, (New York: Dell, 1977); Ted Howard, "Laboratory Fertilization: Is it a First Step to Genetic Manipulation?" *St. Louis Post-Dispatch*, November 21, 1979; Ted Howard and Jeremy Rifkin, "Playing God in the Laboratory: The Politics of DNA Research," *Newsday*, January 25, 1978; Howard and Rifkin, "Cloning: If It's True, It's Truly Fantastic," *Los Angeles Times*, March 14, 1978; Ted Howard, "The Test-Tube Baby: Medical Triumph or Brave New World?" testimony presented before the Ethics Advisory Board of H.E.W., fall, 1978; Charles Frankel, "The Specter of Eugenics," *Commentary*, March, 1974; Jon Beckwith, "Social and Political Uses of Genetics in the U.S.: Past and Present," *Annals of the New York Academy of Sciences*, 265, 1976; Frederick Ausubel, Jon Beckwith and Karen Janssen, "The Politics of Genetic Engineering: Who Decides Who's Defective?" *Psychology Today*, June, 1974; Paul Ramsey, "On In Vitro Fertilization," (Chicago: Americans United for Life, 1979); Lord Ritchie-Calder, "The Tailor Retailored," *1976 Britannica Book of the Year*, Special Supplement; Joseph Fletcher, *The Ethics of Genetic Control* (Garden City, NY: Anchor Books, 1974); Joshua Lederberg, "Experimental Genetics and Human Evolution," *The Bulletin of the Atomic Scientists*, October, 1966; Leon Kass, "New Beginnings of Life," in Michael Hamilton, ed., *The New Genetics and the Future of Man* (Grand Rapids, Mich: Eerdmans); James D. Watson, "The Future of Asexual Reproduction," *Intellectual Digest*, Vol. 2, no. 2, 1971; Kenneth Guentert, "Will Your Grandchild Be a Test Tube Baby?" *U.S. Catholic*, June, 1977; James F. Danielli, "Artificial Synthesis of New Life Forms," *The Bulletin of the Atomic Scientists*, December, 1972; Marc Lappé, "Moral Obligations and the Fallacies of Genetic Control," *Theological Studies*, vol. 33, no. 3 (September, 1972); Caryl Rivers, "Genetic Engineering: Now That They've Gone Too Far, Can They Stop?" *Ms.*, June, 1976; Donald Huisingh, "Should Man Control His Genetic Future?" *Zygon*, 42 (February, 1969); Robert Sinsheimer, "The Dawn of Genetic Engineering," address to the Genetics Society of America (August, 1975).



Today, molecular biologists probe and analyze the basic chemical substances of living matter. Human genes are being mapped, photographed, analyzed, transplanted, synthesized. Geneticists gaze into the very mysteries of life, searching for the keys that will one day unlock the doors to the biological control of the future of humanity. Many such keys have already been found. To Harvard Nobel laureate, Salvador Luria, "the relevant point . . . is that all essential features of the genetic process, insofar as they have been clarified, have turned out to be interpretable in strictly biochemical terms. What molecular biologists have done is to make the genetic mechanism directly available to chemical experimentation."[26]

Dr. James F. Crow, former chairman of the biology department of the University of Wisconsin, says that "it is clear that biological and chemical possibilities for influencing human evolution and development are certain to come, probably before we have thought them through."[27] A report issued by the Subcommittee on Science, Research and Development of the House of Representatives is even more explicit: "The science of genetics is rapidly mov-

[26]Salvador Luria, "Modern Biology: A Terrifying Power," *The Nation*, October 20, 1969.

[27]Quoted in *Bioscience*, December, 1966.

ing out of the realm of theoretical research and into the more politically sensitive region of applied science. The technological capability to alter the course of human evolution is relatively close at hand."[28]

In the last analysis, recombinant DNA and other genetic engineering techniques will not be confined to mere microorganisms. Significant breakthroughs are now being made that will lead to human genetic engineering. In October of 1979, Dr. W. French Anderson of the National Heart, Lung and Blood Institute, announced that his team of researchers had achieved a major breakthrough by successfully injecting a single gene into a defective living cell, "curing" that cell's genetic flaw. Anderson's success is an important step toward the day when human genetic manipulation will be possible.[29]

In human terms, the Journal of the American Medical Association defines genetic engineering as follows:

> "The popular term, genetic engineering, might be considered as covering anything having to do

[28] *Genetic Engineering: Evolution of a Technological Issue,* Report to the Subcommittee on Science, Research and Development of the Committee on Science and Astronautics, House of Representatives, November, 1972.

[29] Harold Schmeck, "Injection of a Gene Cures Flaw in Cell," *The New York Times,* October 10, 1979. Other relevant articles on recent important breakthroughs in genetic research include: Mary Jane Schier, "Gene Research: Unique Achievement Reported Here," *Houston Post,* October 17, 1979; "Doctors Isolate Single Gene; Step in Birth Defects Study," *The Washington Post,* July 28, 1978; Jack D. Griffith, "DNA Structure: Evidence from Electron Microscopy," *Science,* vol. 201 (11 August 1978); "Gene Injection Remedies Cell Defect," *Science News,* vol. 116.



> with the manipulation of the gametes or the fetuses, for whatever purpose, from conception other than by sexual union, to treatment of disease in utero, to the ultimate manufacture of a human being to exact specification . . . Thus, the earliest procedure in genetic engineering . . . is artificial insemination, next . . . artificial fertilization . . . next artificial implantation . . . and finally, what is popularly meant by genetic engineering, the production — or better the biological manufacture — of a human being to desired specifications."[30]

Significantly, with the exception of the full-scale manufacture of human beings to desired specifications, all of the processes outlined by JAMA have already been accomplished with human beings.

As we embark upon this course of the technological alteration of the human germplasm, and the germplasm of other mammals such as cattle, significant moral and ethical issues are raised. Some observers worry that the very technology that ushers in the Genetic Age will inevitably violate the human spirit. Ethicist and author Dr. Leon Kass, himself a molecular biologist trained at Harvard, argues that "increasing control over the product is purchased by the increasing depersonalization of the process."[31] Jacques Ellul, the French philosopher and social critic, predicts that we will eventually become overwhelmed and consumed by the biological technology we create: "When technique enters into every area of life, including the human, it ceases to be external to man and becomes his very substance. It is no

[30] "Genetic Engineering: Reprise," *Journal of the American Medical Association,* vol. 220, no. 10 (June 5, 1972).

[31] Leon Kass, "Making Babies — The New Biology and the 'Old' Morality," *The Public Interest,* Winter, 1972.

longer face to face with man, but is integrated with him, and it progressively absorbs him."[32] Pursuing Ellul's line of thought, Dr. Salvador Luria asks, "When does a 'repaired' or 'manufactured' man stop being a man . . . and become a robot, an object, an industrial product?"[33]

Dr. Luria's comments are highly relevant to the case at hand, for one day it *will* be possible to convert higher organisms, including human beings, into "industrial products" just as microorganisms are being so engineered today. A ruling in 1980 favoring patents on living organisms will open the way to patents of higher forms of life in the years to come.

The majority in the lower court has naturally contended that such is not the case. Judge Rich (October 6, 1977) has written in his Bergy ruling: "As for the . . . fears that our holding will of necessity, or 'logically,' make all new, useful and unobvious species of plants, animals and insects created by man patentable, we think the fear is far-fetched." Elsewhere in the opinion, the majority ruled that the Bergy and Chakrabarty microorganisms are "much more akin to inanimate chemical compositions such as reactants, reagents, and catalysts than they are to horses and honeybees, or raspberries and roses."[34]

PBC believes that the majority was short-sighted and relied upon dubious logic in arriving at these conclusions. As Judge Miller correctly noted in his dissent to the majority opinion:

> Such a distinction is purely gratuitous and clearly erroneous. The nature of organisms, whether

[32]Jacques Ellul, *The Technological Society (New York: Vintage, 1974).*

[33]Luria, ibid.

[34]563 F.2d 1031. As reported in Solicitor General's Petition for Writ of Cert. to Supreme Court, p.124a.



> microorganisms, plants or other living things, is fundamentally different from that of inanimate chemical compositions. For example, both the microorganisms claimed herein and honeybees are alive, reproduce, and act upon other materials to form technologically useful products (lincomycin and honey, respectively). This cannot be said of chemical compositions.[35]

The thing which sets living organisms apart from nonliving entities is their very "aliveness." If this basic fact is not accepted, then there is no place to draw the line concerning which living things are patentable and which are not. Either all forms of life altered through genetic engineering are patentable subject matter under 35 U.S.C. 101, or none are. The logic of patenting life holds that altered living organisms which perform functions similar to nonliving chemical compositions are patentable. If this view is adopted, there is then no viable distinction between lower and higher organisms. After all, a horse (a living organism), can perform a function similar to a tractor (a man-made composition of matter): both can pull a plow. Should then genetically altered or asexually reproduced horses be subject to patenting? If patents are awarded on microorganisms, the answer must be 'yes.'

Ironically, the impossibility of differentiating between genetically altered lower and higher life forms is best articulated in *amicii* presented the lower court by the Regents of the University of California and Genentech, both of which support life form patents.

Noting that recent research with viruses has led some scientists to ponder whether these organisms are actually to be classified as dead or alive – as living beings or as chemical material – the University quotes one scientist as saying,

[35]*Id.*

"The gap between life and nonlife has disappeared." The University goes on to assert:

> Recognition of the difficulty that skilled scientists are experiencing in drawing a bright line between life and its absence effectively destroys the argument that life itself is not only *the essential characteristic* of *any* living being – even a microorganism – but *the one* which, so long as unaltered precludes patentability. Surely where the line between life and nonlife is so fine as to baffle even the experts in the art and at times cannot be drawn with conviction, compositions of matter or manufactures near the periphery cannot conveniently be deemed patentable or unpatentable on so ephemeral a ground."[36]

A microorganism, the University argues, is so close to "the periphery" of life that there should be no obstacle to patenting it, and indeed to proclaiming it non-living. A microorganism may be a thing of small consequence to most people. But where and how will we draw the line once we embark on a course of classifying life at "the periphery" as so inconsequential that it is patentable material? Perhaps Genentech, in its own amicus brief supporting patents for life forms, has provided an answer. The company notes that more than a century ago, Claude Bernard observed:

> "(A) created organism is a machine which necessarily works by virtue of the physico-chemical properties of its constituent elements. Today we differentiate three kinds of properties exhibited in the phenomena of living beings: physical properties, chemical properties, and vital properties. But the term 'vital properties' is itself only provisional; because we call properties vital

[36]In brief amicus curiae of the University of California, Berkeley, in the matter of the application of Malcolm E. Bergy, et al., pp. 15-16.



> which we have not yet been able to reduce to physio-chemical terms; but in that we shall doubtless succeed some day."[37]

*Here we confront the essence of the matter which is inherent in the case now before the Court.* To justify patenting living organisms, those who seek such patents must argue that life has no "vital" or sacred property; that all of life's properties can ultimately be reduced to the "physico-chemical." But once this is accomplished, all living material will be reduced to an arrangement of chemicals, or mere "compositions of matter." When this happens, all life will move toward that "periphery" in which the University of Californa claims life does not have to be treated as life at all.

This is the modern scientific view of man and woman. Reproduction is analyzed in terms of the interaction of chemical units contained in the sperm and egg; the brain is mapped and manipulated with electronic and chemical stimulants to "explain" how thought processes work; sociobiologists reduce human emotions like love and altruism to an ill-defined genetic base.

The case before the court may not appear to involve the life and death issues and passions of abortion, euthanasia or brain death rulings. Nonetheless, appearances aside, this case actually eclipses the import of these others because, in reaching a decision, a precedent-setting determination of the very nature of life will have to be decided upon. Whether such a definition is explicitly stated by the Court or not, hardly matters. If a ruling in favor of patenting genetically engineered living organisms is forthcoming,

[37]In brief amicus curiae of Genentech, in the matter of the application of Ananda M. Chakrabarty, p. 8.

then manufactured life – high and low – will have been categorized as less than life, as nothing but common chemicals.

It is no exaggeration to state that those who favor the granting of patents in this case would welcome just such a definition of manufactured life being of less value than naturally occurring life. The American Patent Law Association brief in support of patents, argued below:

> The distinguishing characteristic of a product of nature is not "life" but its existence without the intervention or industry of man and the distinguishing characteristic of a manufacture is not its 'non-life' but its existence through industry of man. The bar to patentability for natural products involves not life but lack of novelty.
>
> "History has shown that the interjection of differentiations based on a mystical 'life' component are seldom scientifically valid.[38]

This is the internal logic that comes to be adopted once *any* forms of living organisms are deemed patentable. If this Court rules in favor of life form patents, it will serve to institutionalize this reductionist and cold philosophy. Further, a ruling in favor of GE and Upjohn will actually dramatically accelerate the very technological developments which will one day make human genetic engineering a reality.

Dr. Leon Kass provides eloquent testimony to the enormity of what is at stake:

> We have paid some high prices for the technological conquest of nature, but none

[38]In brief amicus curiae of the American Patent Law Association, in the matter of the application of Bergy, et al., pp. 4 and 5.



> perhaps so high as the intellectual and spiritual costs of seeing nature as mere material for our manipulation, exploitation and transformation. With the powers for biological engineering now gathering, there will be splendid new opportunities for a similar degradation of our view of man. Indeed, we are already witnessing the erosion of our idea of man as something splendid or divine, as a creature with freedom and dignity. And clearly, if we come to see ourselves as meat, then meat we shall become. The new technologies for human engineering may well be "the transition to a wholly new path of evolution." They may, therefore, mark the end of *human* life as we and all other humans know it. It is possible that the non-human life that may take our place will in some sense be superior – though I personally think it most unlikely, and certainly not demonstrable. In either case, we are ourselves human beings; therefore, it is proper for us to have a proprietary interest in our survival, and in our survival as human beings. This is a difficult enough task without having to confront the prospect of a utopian, constant remaking of our biological nature with all-powerful means but with no end in view.[39]

[39]Kass, ibid.

## CONCLUSION

For the foregoing reasons, the judgment of the court below should be reversed.

Respectfully submitted,

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## CERTIFICATE OF SERVICE

I hereby certify that on December 13, 1979, I deposited in the United States mail, postage prepaid, three copies of the attached brief Amicus Curiae, addressed to each of the counsel for the Parties listed below:

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